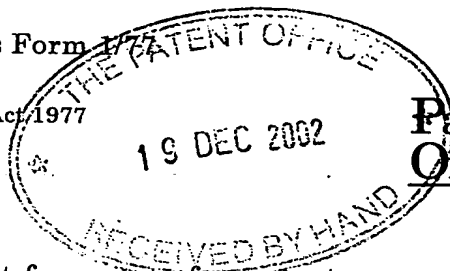






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2.	Patent application number (The Patent Office will fill in this)	0229624.2		19 DEC 2002
3.	Full name, address and postcode of the or of each applicant (underline all surnames)	NOVARTIS NUTRITION AG MONBIJOUSTRASSE 118 3001 BERN SWITZERLAND		
	Patent ADP number (if you know it)	7143563001		
	If the applicant is a corporate body, give the country/state of its incorporation	SWITZERLAND		
4.	Title of invention	Connector device		
5.	Name of your agent (If you have one) "Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	Novartis Pharmaceuticals UK Ltd Patents and Trademarks Wimblehurst Road HORSHAM West Sussex RH12 5AB ADP No 0718522002		
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Date

B. A. Yorke & Co

B.A. Yorke & Co.

19 December 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

Mrs. J. Crook  
020 8560 5847

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DUPLICATE

- 1 -

Connector Device

The present invention relates to a connector device or adaptor, e.g. a sterile connector device or adaptor, allowing connection between the feeding line of an enteral, e.g. nutritional, administration set and a laminated paper packaging system, such as Tetra Brik®, containing medical or nutritional fluids or compositions which can be enterally administered to a patient.

Many individuals in hospitals or nursing homes cannot orally take nourishment or medication. These individuals, or medical patients, typically receive medical fluids containing the required nourishment and/or medication enterally via a patient feeding line of an enteral administration set that is connected to a packaging system containing such medical or nutritional fluids. These medical or nutritional fluids are commonly packaged in flexible packaging systems, such as containers, for example flexible pouches. For economical and other reasons, such pouches may be disadvantageous.

Millions of laminated paper packaging systems, such as Tetra Brik®, are used in food industry. They provide a convenient cost-effective and lightweight paperboard solution, for every type of pourable, e.g. liquid, product. They exist in a myriad of sizes, from 0.2 liter to 1.5 liter, or even larger. Because they are opaque, they are perfect for light-sensitive enterally administrable compositions, for example enterally administrable compositions containing certain vitamins. Typically, medical fluids that are administered to a patient need to be sterile. Laminated paper packaging systems can be sterilized, and therefore can keep even the most perishable liquid foods fresh and nutritious for months, without refrigeration or added preservatives. Finally, the laminated paper packaging systems can be aseptically and air tightly closed, preventing contaminants and/or oxygen from entering the container. Such laminated paper packaging systems may be advantageously used to contain pharmaceutical or nutritional compositions, e.g. enteral medical or nutritional fluids.

However, the existing enteral administration sets are not adapted to being connected, e.g. directly connected, to the existing laminated paper packaging systems. Consequently, medical or nutritional compositions, e.g. fluids, have to be poured into an intermediate container which is then connected to the feeding line of an enteral administration set. This is inconvenient for patients and medical personnel. Moreover sterility is difficult to ensure.

In one aspect the present invention provides a connector device or adaptor suitable for use with an existing enteral administration set and an existing laminated paper packaging system, e.g. which connector device allows the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system through the connector device into the enteral administration set. According to the invention, such connector device may be quickly and easily connected to such a laminated paper packaging system.

In another aspect of the invention, there is provided a connector device suitable for connecting, e.g. directly connecting, an enteral administration set to a laminated paper packaging system.

Such existing enteral administration sets, e.g. feeding lines, e.g. tube feeding lines of enteral administration sets, and existing laminated paper packaging systems, are well-known to one skilled in the art. For example, enteral administration sets are known and commercially available e.g. from Fresenius, Nutricia, Sherwood Medical Company, B. Braun Melsungen or Novartis Nutrition Corporation, e.g. under the trade name Compat® commercially available from Novartis Nutrition Corporation (Minneapolis, Minnesota). Examples for known and commercially available laminated paper packaging systems are Tetra Brik®, Tetra Pak®, Tetra Brik Aseptic®, Tetra Prisma®, Tetra Recart®, Tetra Top®, Tetra Square®, available from Tetra Laval Holding and Finance SA, as well as Elopak®, Combiblok®, Pure Pak®, or those available from Toppan.

In a further aspect of the invention there is provided a connector device for an enteral administration set, e.g. the feeding line of an enteral administration set, and a laminated paper packaging system, which provides a tight, e.g. a liquid-tight, air-tight, e.g. oxygen-tight, and/or sterile connection between the enteral administration set and the laminated paper packaging system. According to the present invention, there is provided a closed system consisting of a connector device for an enteral administration set, e.g. the feeding line of an enteral administration set, and a laminated paper packaging system, which connector device provides an oxygen-tight and/or sterile connection directly to a laminated paper packaging system.

In yet a further aspect of the present invention there is provided an inexpensive and easily manufactured connector device for an enteral administration set and a laminated paper packaging system.

5       The connector device according to the invention may be reusable or for unique usage.

In another aspect of the invention there is provided a connector device for a laminated packaging system, adapted to simultaneously open, directly or indirectly, the laminated paper packaging system when being connected, e.g. tightly connected, thereto. Such a  
10       connector device may be adapted to be connected, e.g. directly connected, to an enteral administration set, e.g. the feeding line of an enteral administration set.

In a further aspect of the invention there is provided a connector device for a laminated paper packaging system, containing a closure system, e.g. a barrier layer, which  
15       connector device contains at least one means for simultaneously opening, e.g. breaking, the closure system of the laminated paper packaging system when being connected, e.g. tightly connected, thereto.

In one embodiment of the invention, such a connector device may be adapted to be  
20       connected, e.g. directly connected, to an enteral administration set, e.g. the feeding line of an enteral administration set.

In another aspect of the present invention there is provided a connector device for an enteral administration set and a laminated paper packaging system, containing a closure  
25       system, e.g. a barrier layer, comprising:

- (a) at least one means adapted to fit to the laminated paper packaging system, e.g. in the area of the closure system, optionally
- (b) at least one means adapted to provoke directly or indirectly the opening of, e.g. to break, the closure system of the laminated paper packaging system, in particular when  
30       connected, e.g. tightly connected, to the laminated paper packaging system, optionally
- (c) at least one means to allow filtration and/or penetration of outside air, e.g. outside filtered air, into the laminated paper packaging system when the connector device is connected, e.g. tightly connected, to the laminated paper packaging system, and optionally,

(d) at least one means adapted to fit to an enteral administration set, e.g. to the feeding line of an enteral administration set.

In a further aspect of the invention there is provided a connector device for an enteral administration set and a laminated paper packaging system comprising:

- (a) a section adapted to fit to the laminated paper packaging system, optionally
- (b) a section adapted to fit to the enteral administration set, e.g. a thread wall portion, and optionally
- (c) means to allow filtration and/or penetration of outside air, e.g. outside filtered air, when the connector device is connected to the laminated paper packaging system.

In a further aspect of the invention there is provided a connector device for an enteral administration set and a laminated paper packaging system, containing a closure system, e.g. a barrier layer, comprising at least one means adapted to fit to the enteral administration set, e.g. to the feeding line of the enteral administration set; at least one means adapted to fit to the laminated paper packaging system, e.g. in the area of the closure system; and optionally at least one means adapted to provoke directly or indirectly the opening of, e.g. to break, the closure system of the laminated paper packaging system, in particular when connected, e.g. tightly connected, to the laminated paper packaging system. According to the invention, the connector device may also contain at least one means to allow penetration and/or filtration of outside air, e.g. outside filtered air, into the laminated paper packaging system when the connector device is connected, e.g. tightly connected, to the enteral administration set and the laminated paper packaging system.

In yet a further aspect of the invention, there is provided a connector device for an enteral administration set and a laminated paper packaging system containing a closure system, such connector device containing means, e.g. a tampering system, adapted to provide visible tamper signal indicating that the connector device has been connected to and/or has opened the laminated paper packaging system.

In one embodiment of the invention, the connector device may consist of one unit, e.g. made entirely of a single material, for example an opaque or transparent material. In another embodiment of the invention, the connector device may be a kit-of-part connector device, i.e. made of independent sections, e.g. made of different material, adapted to be assembled,



e.g. just before use, such as a section adapted to fit to a laminated paper packaging system and/or a section adapted to fit to the enteral administration set, e.g. a thread wall portion. The section of such a kit-of-part connector device which is adapted to fit to the feeding line of an enteral administration set may be connected, e.g. permanently or irreversibly  
5 connected to the enteral administration set.

In another aspect of the present invention there is provided a device comprising an enteral administration set and a connector device connected, e.g. permanently or irreversibly connected, thereto for a laminated paper packaging system, containing a closure system,  
10 e.g. a barrier layer. Optionally such a device may comprise at least one means adapted to provoke directly or indirectly the opening of, e.g. to break, the closure system of the laminated paper packaging system when connected, e.g. tightly connected, thereto. Such a device may further comprise at least one means to allow filtration and/or penetration of outside air into the laminated paper packaging system when the connector device is  
15 connected, e.g. tightly connected, thereto.

In yet another aspect of the present invention there is provided a device comprising a laminated paper packaging system, containing a closure system, e.g. a barrier layer, and a connector device connected, e.g. permanently or irreversibly connected, thereto for an  
20 enteral administration set. Optionally such a device may comprise at least one means adapted to provoke directly or indirectly the opening of, e.g. to break, the closure system of the laminated paper packaging system. Such a device may further comprise at least one means to allow filtration and/or penetration of outside air, e.g. of filtered outside air, into the laminated paper packaging system when the device is connected, e.g. tightly connected,  
25 thereto.

According to the invention, the connector device and the device as hereinabove described may be sterilisable, e.g. retortable or sterilisable for example by ethyleneoxide (ETO), gamma-radiation, beta-radiation, peroxide or any other suitable chemical agent  
30 known to one skilled in the art.

In yet a further aspect of the present invention there is provided an enteral administration set, e.g. a feeding line of an enteral administration set, connected to a

laminated paper packaging system, e.g. of the type Tetra Brik® or Tetra Pak®, containing a nutritional or medical composition through the connector device as hereinabove described.

5 The accompanying drawings, which are incorporated into and constitute part of the specification, illustrate exemplary embodiments of the present invention.

FIG.1 is an exploded cross-sectional view of a connector device connected to a feeding line of an enteral administration set and a laminated paper packaging system in accordance with an embodiment of the present invention;

FIG. 2 is an enlarged cross-sectional view of the connector device depicted in FIG.1.

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As used herein, the term "enteral administration set" encompasses all components of the feeding line located between the connector device as hereinabove described, and the patient, for example the tube feeding line, and optionally a plastic bag, e.g. a transparent plastic bag. Such a plastic bag may be collapsible. It may also contain air, e.g. filtered air.  
15 Such a plastic bag is known to one skilled in the art.

In one embodiment of the invention, such a plastic bag may be reversibly or permanently, e.g. irreversibly connected to the connector device. The irreversible connection of the connector device to the plastic bag may be made by methods including, but not limited to, heat induction, ultrasonic welding and friction welding or any other methods as known in the art.  
20

Referring to FIGS.1 and 2, the connector device (1) may be connected to the feeding line (2) of an enteral administration set, e.g. a feeding line of an enteral administration set (3), and to a laminated paper packaging system, (4). The connector device may contain: a section (5) which is adapted to the feeding line (2) of the enteral administration set (3); on the opposite side a section (6) adapted to be connected to the laminated paper packaging system (4); and optionally venting means comprising a valve system (7) positioned such as to allow the outside air to penetrate into the laminated paper packaging system when the connector is connected, e.g. tightly connected, to the enteral administration set (3) and to the laminated paper packaging system (4). According to the present invention, the venting means (7) may also contain an air filter, e.g. a bacterial filter (9), to prevent non-filtered air or contaminants, e.g. bacteria, from entering the feeding line and/or the laminated paper packaging system. It will be appreciated that such valve system and/or such air filter may  
25  
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also be positioned in the feeding line of the enteral administration set, or in the laminated paper packaging system. Preferably, such valve system and such air filter are positioned in the connector device, even more preferably in section (6) of the connector device which is adapted to be connected to the laminated paper packaging system.

5

In one aspect of the invention, the venting means may comprise an air passageway allowing air, e.g. filtered air, to penetrate into the laminated paper packaging system, optionally without penetrating into the fluid passageway. The passage of the compositions contained in the laminated paper packaging system from the laminated paper packaging system through the air passageway may be prevented, e.g. by a flexible membrane positioned adjacent to the inner opening of the air passageway, as described for example in US 4,997,429, which is incorporated herein by reference. Such venting means are known and commercially available in existing enteral feeding sets, e.g. of the type Compat® from Novartis Nutrition Corporation (Minneapolis, Minnesota).

15

Section (5) of the connector device adapted to the enteral administration set (3) may be connected to the feeding line (2) through a thread (8), e.g. screw thread. Alternatively, a snap-fit assembly may be used to connect the connector device to the feeding line (2). A circumferential tab section projecting from the section of the connector device suited to connect the feeding line may engage a rim at the end of the feeding line, securing the connector device to the feeding line. After engagement, the connector device may be further adhered to the feeding line, e.g. by sonic welding.

20

In a further embodiment, the connector device, e.g. section (5) of the connector device may be connected, e.g. permanently or irreversibly connected, to the feeding line by sealing, e.g. sonic welding (not shown).

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For the purpose of the present invention, the term "compositions" encompasses nutritional and medical compositions, e.g. nutritional and medical fluids, and in particular enteral compositions. According to the invention, these compositions are contained in a laminated paper packaging system.

30

The laminated paper packaging system (4) according to the invention may be for example of the type Tetra Brik®, Tetra Brik Aseptic®, Tetra Pak®, Tetra® Prisma, Tetra

Recart®, Tetra Square®, Tetra Top®, Elopak®, Combiblok®, Pure Pak®. According to the invention, the laminated paper packaging system may be from 0.125 liter to 2 liters volume, preferably from 0.200 liter to 1 liter volume. Most preferred sizes include 0.200, 0.250 and 1 liter.

5

Such laminated paper packaging systems may comprise layers of fibrous material, such as paper or cardboard, which are coated on either side with a thermoplastic material such as polyethylene. On the side of the laminated paper packaging material which is destined to be in contact with the composition, there may be also a layer of barrier material, such as e.g. aluminum foil, which may also be coated with a thermoplastic layer. Such laminated paper packaging systems are disclosed for example in US 6,223,924, which is hereby incorporated by reference. Techniques to sterilize such laminated paper packaging systems are known to one skilled in the art. Packaging machines have been developed to aseptically fill and seal such laminated paper packaging systems, e.g. sterilized laminated paper packaging systems, with sterilized food products or compositions.

15

Such laminated paper packaging systems, may contain a reduced thickness portion, e.g. a portion where a hole is formed through some of the layers of the laminated paper packaging materials, and where one or more aluminum and/or polyethylene barrier layers extend over the hole (not shown). Such a reduced thickness portion may be closed, e.g. hermetically and/or aseptically closed, by a closure system (10). Alternatively, the laminated paper packaging system may contain a hole not covered by any layers of the laminated paper packaging materials. Such laminated paper packaging systems may also be closed, e.g. hermetically and/or aseptically closed, by a closure system (10).

25

According to the invention, the term "closure system" refers to a removable or breakable closure system. As used herein the term "breakable" encompasses breakable by rupturing, perforating and/or tearing, e.g. completely or partially, providing an opening in the closure system of the laminated paper packaging system, sufficiently extended to permit composition flowing from the laminated paper packaging system through the connector device into the feeding line.

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The closure system according to the invention may consist of a barrier layer (10) defeatable in some manner, for example by removal or by penetration, e.g. a seal, e.g. a foil

seal. In one embodiment of the invention such a closure system may be hermetic and/or aseptic. Preferably, the barrier layer, e.g. the foil seal, is adhesively hot sealed, e.g. aseptically sealed, to the laminated paper packaging system, e.g. by flowing a heated foodgrade hot melt adhesive between the barrier layer and the laminated paper packaging system, where the barrier layer, e.g. the foil seal, is in contact with the laminated paper packaging system. This closure system, e.g. the barrier layer, may be opaque. It may also be made of a material that has no or low permeability to air, e.g. to oxygen. Suitable barrier layers are known to one skilled in the art and include, but are not limited to, for example, polymeric membrane, aluminum foil or thin plastic. It will be appreciated that one skilled in the art is fully enabled to select a suitable material.

The closure system of the laminated paper packaging system, may also consist of a frame-like member (11), integratable within the laminated paper packaging system, preferably affixed thereto, circumscribing the barrier layer. The frame-like member of the laminated paper packaging system may be of the type associated with spin® cap or stream® cap, available e.g. from Tetra Laval Holding and Finance SA. Such frame-like members are known to one skilled in the art, and are described e.g. in EP0947433, US 6,382,462, US 6,422,412 or US 6,223,924, which are hereby incorporated by reference. The frame-like member may be integrated within the laminated paper packaging system by techniques known to one skilled in the art, e.g. by application of hot melt adhesive, microflame welding or laser welding. Such a frame-like member (11) may be closed by a second barrier layer, e.g. a foil, e.g. an aluminum foil, removable therefrom. In another embodiment of the invention, the frame-like member (11) may be closed by a standard cap, e.g. a reclosable cap; e.g. screw or push cap. In this case, access to the barrier layer covering the opening of the laminated paper packaging system may be made after removing the cap from the frame-like member.

According to the present invention, the connector device (1) may be connected to the laminated paper packaging system (4) through the frame-like member (11) thereof, e.g. through an internal thread (12a), e.g. screw thread, of the connector device interacting with an external thread (12b), e.g. screw thread of the frame-like member (11), or any other suitable structure known in the art.

In one embodiment of the invention, the section of the connector device which is adapted to fit to a laminated paper packaging system, has diameter, e.g. internal diameter, comprised between about 1.0 cm and about 3.5 cm, preferably between about 1.3 cm and about 3.0 cm, more preferably between about 1.5 cm and about 2.5 cm and even more preferably between about 1.8 cm and about 2.3 cm. The most preferred diameter, e.g. internal diameter of the section of the connector device adapted to fit to the laminated paper packaging system is about 2 cm.

In one embodiment of the invention, the connector device (1) contains an opening system (13), e.g. a breaking system, adapted to open, e.g. break, the closure system, e.g. the barrier layer (10), of the laminated paper packaging system (4), e.g. creating a passageway for the composition flowing from the laminated paper packaging system through the connector device to the enteral feeding line. This opening, e.g. breaking, system may comprise one or more cutting means, e.g. spikes (14), cutting teeth, cutter or any other suitable structure known to one skilled in the art.

In one embodiment of the invention, the cutting means are projecting means. The length, position and number of the cutting means, e.g. the projecting means, may be adapted to open, e.g. break, the closure system of the laminated paper packaging system when the connector device is connected, e.g. tightly connected thereto. Alternatively, the cutting means, e.g. projecting means, may extend beyond the bottom of section (6) adapted to be connected to the laminated paper packaging system.

According to the invention, the opening, e.g. breaking, system of the connector device may be offset from the center, e.g. center axis, thereof.

In another embodiment of the invention, the opening, e.g. breaking, system of the connector device may be placed in the center of the connector device. For example, the opening, e.g. breaking, system of the connector device may be in prolongation from the section of the connector device adapted to be connected to the feeding line of the enteral administration set.

According to the invention, the opening, e.g. breaking, system of the connector device may be hollow, e.g. may include a fluid passageway permitting composition flowing from the

laminated paper packaging system through the connector device into the enteral administration set, e.g. the feeding line of the enteral administration set.

5 In another embodiment of the invention, the opening, e.g. breaking, system of the connector device may consist of a tubular member provided inside the connector device and adapted to be engaged with the frame-like member (11) of the laminated paper packaging system, e.g. by containing external threads capable of connecting internal threads present in the frame-like member (11). Such a tubular member may contain, e.g. on its lowermost edge, at least one cutting means, e.g. cutting tooth, adapted to break, the closure system, 10 e.g. the barrier layer (10), of the laminated paper packaging system, upon engagement of the tubular member with the frame-like member. Such opening systems are known to one skilled in the art, e.g. associated with stream® cap, available e.g. from Tetra Laval Holding and Finance SA, e.g. as described in EP0947433, which is hereby incorporated by reference.

15

The opening, e.g. breaking, system of the connector device may directly open, e.g. break, the closure system, e.g. the barrier layer (10), of the laminated paper packaging system, when connecting, e.g. tightly connecting, the connector device (1) thereto. Such a contact may be made by pressing the connector device (1) to the laminated paper packaging 20 system (4), or alternatively by screwing it, onto the frame-like member (11) of the laminated paper packaging system.

In another embodiment of the invention, the closure system, e.g. barrier layer (10), of the laminated paper packaging system (4) may be opened, e.g. broken, by an opening, e.g. 25 breaking, system (15) associated with, e.g. incorporated into, the frame-like member (11) of the laminated paper packaging system (4). Such an opening, e.g. breaking, system may be movable, e.g. from a first position where it does not open, e.g. break, the closure system of the laminated paper packaging system, e.g. where it is not into contact with the closure system, to a second position where it opens, e.g. breaks, the closure system, e.g. where it 30 protrudes below the frame-like member (11). Preferably the opening, e.g. breaking, system may be formed integrally with an elastic hinge. The elastic hinge may be formed integrally with the frame-like member. Such opening, e.g. breaking, systems, associated with laminated paper packaging systems, are known in the art and include, but are not limited to, for example, opening, e.g. breaking systems connected to the frame-like member associated

with caps, e.g. twist-off or screw caps, e.g. of the type spin® cap or stream® cap, or snap-on caps. The opening, e.g. breaking, system may comprise or consist of opening means, e.g. projecting means, e.g. spikes (14), cutting teeth, cutter. Preferably the opening system of the laminated paper packaging system (4), is of the type of the breaking system  
5 connected to the frame-like member associated with spin® cap or stream® cap, e.g. as described in US 6,223,924, EP0947433, US 6,382,462 or US 6,422,412, which are hereby incorporated by reference. which are hereby incorporated by reference.

According to the present invention, the opening, e.g. breaking, system of the laminated  
10 paper packaging system (4) may be indirectly opened, e.g. triggered, by connecting the connector device, i.e. section (6) of the connector device, to the laminated paper packaging system, e.g. to the frame-like member (11) thereof.

In one embodiment of the invention, section (6) of the connector device, adapted to  
15 being connected to the laminated paper packaging system, contains at least one triggering, e.g. actuation, system (16) capable of interacting with the opening, e.g. breaking, system (15) of the laminated paper packaging system (4) to shift it in direction to the closure system (10), e.g. the barrier layer, provoking its opening, e.g. its break. In one embodiment, the triggering, e.g. actuation, system may provoke the move of the opening, e.g. breaking,  
20 system of the laminated paper packaging system from the first position to the second position as defined hereinabove, upon connecting the connector device to the laminated paper packaging system. Such triggering system may be an extending, e.g. a downwardly extending, system. It may consist of or comprise at least one means, e.g. arm or cam, capable of interacting with the opening, e.g. breaking, system (15) of the laminated paper  
25 packaging system (4), for example by leverage or reverse thread, e.g. screw thread. Such triggering systems are known to one skilled in the art. Preferably the triggering, e.g. actuation, system of the connector device according to the invention is of the type of the actuation system associated with spin® cap or stream® cap, e.g. as described in US6,223,924, US6,422,412 or US6,382,462 which are incorporated herein by reference. In  
30 one embodiment of the invention, such a triggering system may be recessed from the closure system, e.g. the barrier layer, of the laminated paper packaging system to ensure that it provokes the opening, e.g. breaking, of the closure system, e.g. the barrier layer, only when the connector device is connected, e.g. tightly connected to the laminated paper packaging system.



According to the present invention, the connector device may contain a tampering system adapted to indicate that the laminated paper packaging system has been opened and/or cannot be closed anymore. Such system may comprise an indicator member, associated with section (6) of the connector device by breakable connection, e.g. by means of bridges, which connection may be permanently or irreversibly broken when the connector device is connected to the laminated paper packaging system, e.g. to the frame-like member thereof (not shown). Such tampering systems are known to one skilled in the art, and are described e.g. in US 6,223,924, which is hereby incorporated by reference. In another embodiment of the invention, the tampering system may comprise means provided in the connector device, e.g. in the tubular member associated with the connector device, such means being adapted to move unidirectionally over the closure system of the laminated paper packaging system, e.g. over the frame-like member of the closure system. Such means may comprise indentations, e.g. indentations configured in a saw-tooth manner adapted to move unidirectionally over e.g. a ratchet pawl provided in the frame-like member of the closure system, thereby preventing removal of the connector device from the laminated paper packaging system. Such means may be known to one skilled in the art and are described e.g. in EP0947433, which is hereby incorporated by reference.

The tightness between the connector device (1) and the laminated paper packaging system (4), may be ensured by means, e.g. systems, known in the art, e.g. applied either on top, inside or outside of the connector device, such as so-called "olive tightness type", by gasket, by foam or elastomere, or by direct top contact. It will be appreciated that one skilled in the art is fully enabled to select a suitable tightness system.

In a further embodiment of the invention, the connector device may be reversibly or permanently, e.g. irreversibly connected to the feeding line of an enteral administration set. The irreversible connection of the connector device to the feeding line may be made by methods including, but not limited to, application of hot melt adhesive, heat induction, ultrasonic welding and friction welding or any other methods as known in the art. In this case the appropriate material of the connector device may be capable of forming a seal, e.g. airtight and/or liquid-tight seal, with the material from which the feeding line of the enteral administration set is made. The connector device may be molded to the feeding line of an enteral administration set to form one single unit.

The connector device of the present invention may be made from a plastic or polymeric material, including but not limited to polyolefin, e.g. polypropylene or polyethylene. The connector device of the present invention may be made from a material that has low permeability to oxygen. In one embodiment of the invention, the connector device may be opaque. Alternatively, the connector device of the present invention may be transparent, or may contain a portion which is transparent, e.g. the section adapted to be connected to the enteral feeding line.

A cap or a seal may be placed over the external ends of the connector device, to prevent contamination of the connector device before use. For example, a cap may be thread, e.g. screw thread, to the section of the connector device adapted to connect the feeding line, and/or to the section of the connector device adapted to connect the laminated paper packaging system. Such a cap may be removed before connecting the connector device to the feeding line and/or to the laminated paper packaging system.

The connector device as described hereinabove may also be reversibly or permanently, e.g. irreversibly, connected to the laminated paper packaging system, or to the enteral administration set, e.g. to the feeding line of the enteral administration set. The irreversible connection of the connector device to the laminated paper packaging system may involve locking means provided in the connector device, e.g. in the tubular member associated with the connector device, e.g. as described in EP0947433, which is hereby incorporated by reference.

Preferably, the connector device as described hereinabove is permanently or irreversibly connected to the enteral administration set, e.g. to the feeding line of the enteral administration set.

Hence, the present invention also pertains to a device comprising a connector device as hereinabove described connected to an enteral administration set, e.g. the feeding line of an enteral administration set. The connector device as described hereinabove may be sterilized when connected to the feeding line, e.g. together with the feeding line. Alternatively, it may be sterilized separately from the feeding line.

In another aspect the present invention also pertains to a device comprising a connector device as hereinabove described connected to a laminated paper packaging system, e.g. a Tetra Brik® or Tetra Pak®.

- 5           The connector device as hereinabove described allows convenient, safe, and economically advantageous administration of a medical or nutritional composition to a patient in need thereof.

- 10           In yet a further aspect the present invention, there is provided a use of a laminated paper packaging system in enteral tube feeding, which use comprises connecting, e.g. directly connecting, a laminated paper packaging system to an enteral administration set via the connector device as hereinabove described.

Claims

1. A connector device for an enteral administration set and a laminated paper packaging system comprising:
  - 5 (a) means adapted to fit to the enteral administration set,
  - (b) means adapted to fit to the laminated paper packaging system, and optionally
  - (c) means to allow filtration and/or penetration of the outside air when the connector device is connected to the enteral administration set and to the laminated paper packaging system.
- 10 2. A connector device for an enteral administration set and a laminated paper packaging system containing a closure system which connector device comprises:
  - (a) means adapted to fit to the enteral administration set,
  - (b) means adapted to fit to the laminated paper packaging system,
  - 15 (c) means adapted to provoke the opening or break of the closure system, when the connector device is connected to the laminated paper packaging system, and optionally
  - (d) means to allow filtration and/or penetration of the outside air when the connector device is connected to the enteral administration set and to the laminated paper packaging system.
- 20 3. The connector device according to claim 2 wherein the connector device comprises means to simultaneously fit the connector device to the laminated paper packaging system and provoke the opening or break of the closure system.
- 25 4. The connector device according to claim 2 or 3 wherein the connector device comprises an opening or breaking system adapted to provoke the opening or the break of the closure system of the laminated paper packaging system.
- 30 5. The connector device according to any one of claim 4 wherein the opening or breaking system comprises at least one spike.

6. The connector device according to claim 2 or 3 wherein the connector device comprises a triggering system adapted to provoke the opening or break of the closure system of the laminated paper packaging system.
- 5 7. The connector device according to claim 6 wherein the triggering system is a leverage system.
8. A connector device for an enteral administration set and a laminated paper packaging system comprising a frame-like member, which connector device comprises:
- 10 (a) means adapted to fit to the enteral administration set,  
(b) means adapted to fit to the laminated paper packaging system,  
(c) means adapted to trigger a breaking system incorporated into the frame-like member of the laminated paper packaging system, when the connector device is connected thereto, and optionally
- 15 (d) means to allow filtration and/or penetration of the outside air when the connector device is connected to the enteral administration set and to the laminated paper packaging system.
9. A connector device for a laminated paper packaging system containing a closure system which connector device comprises:
- 20 (a) means adapted to fit to the laminated paper packaging system,  
(b) means adapted to provoke the opening or break of the closure system, when the connector device is connected to the laminated paper packaging system, and optionally
- 25 (c) means to allow filtration and/or penetration of the outside air when the connector device is connected to the laminated paper packaging system.
10. A connector device for a laminated paper packaging system comprising a frame-like member, which connector device comprises:
- 30 (a) means adapted to fit to the laminated paper packaging system,  
(b) means adapted to trigger a breaking system incorporated into the frame-like member of the laminated paper packaging system, when the connector device is connected to the laminated paper packaging system, and optionally

(c) means to allow filtration and/or penetration of the outside air when the connector device is connected to the laminated paper packaging system.

5 11. A connector device suitable for connecting an enteral administration set to a laminated paper packaging system.

12. A connector device for a laminated packaging system and optionally an enteral administration set, adapted to simultaneously open the laminated paper packaging system when being connected thereto.

10 13. The connector device according to any preceding claim having a diameter of between about 1.0 and about 3.5 cm.

15 14. The connector device according to any preceding claim wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.

15. Use of a laminated paper packaging system in enteral tube feeding, which use comprises connecting a laminated paper packaging system to an enteral administration set via a connector device.

20 16. A device comprising an enteral administration set and the connector device of any one of claims 1 to 14 connected thereto.

25 17. A device comprising a laminated paper packaging system and the connector device of any one of claims 1 to 14 connected thereto.

18. The device according to claim 17 wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.

30 19. An enteral administration set connected to a laminated paper packaging system through a connector device of any one of claims 1 to 14.

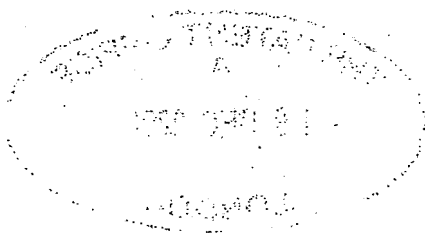
20. Method of enterally administering to a patient in need thereof a medical or nutritional composition contained in a laminated paper packaging system which method

comprises connecting the feeding line of an enteral administration set to the laminated paper packaging system through a connector device according to any one of claims 1 to 14.

- 5     21. The method according to claim 18 wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.
- 10     22. A connector device, device or enteral administration set as claimed in any one of claims 1 to 14, claims 16 to 18 or claim 19, substantially as hereinbefore described with reference to any one of the accompanying figures.

ABSTRACT

The present invention relates to a connector device suitable for connecting an enteral administration set to a laminated paper packaging system containing enterally administrable  
5 medical or nutritional food.





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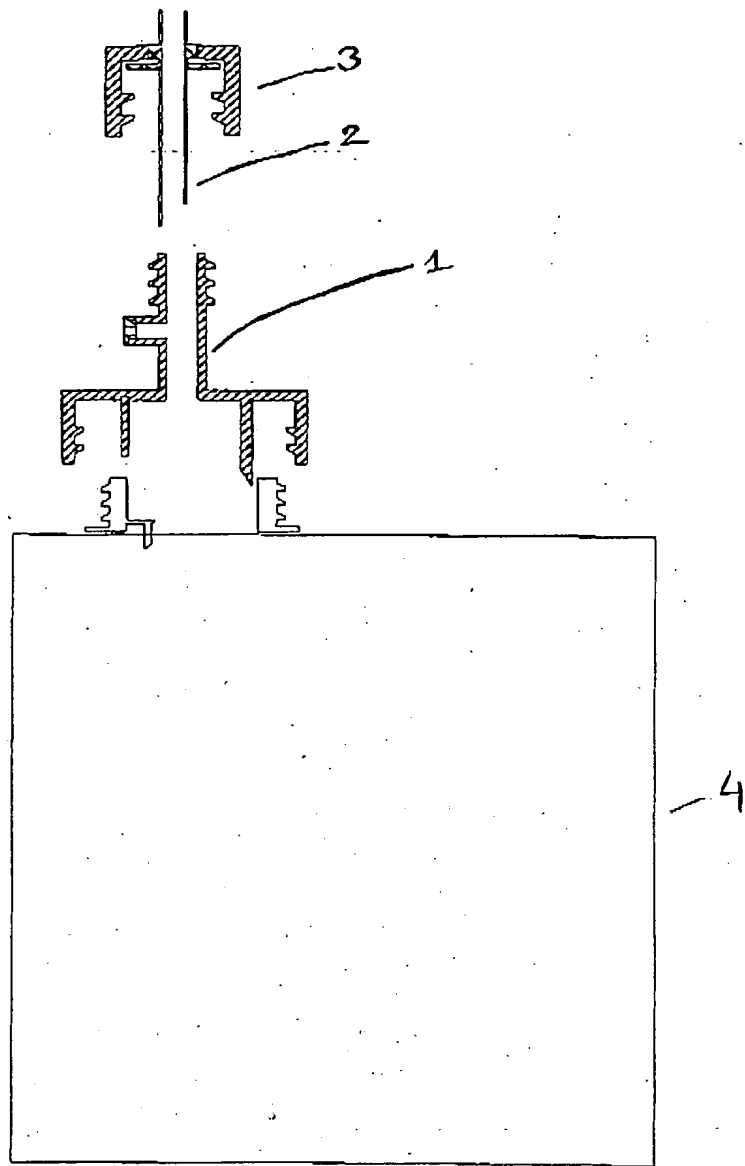


FIG. 1

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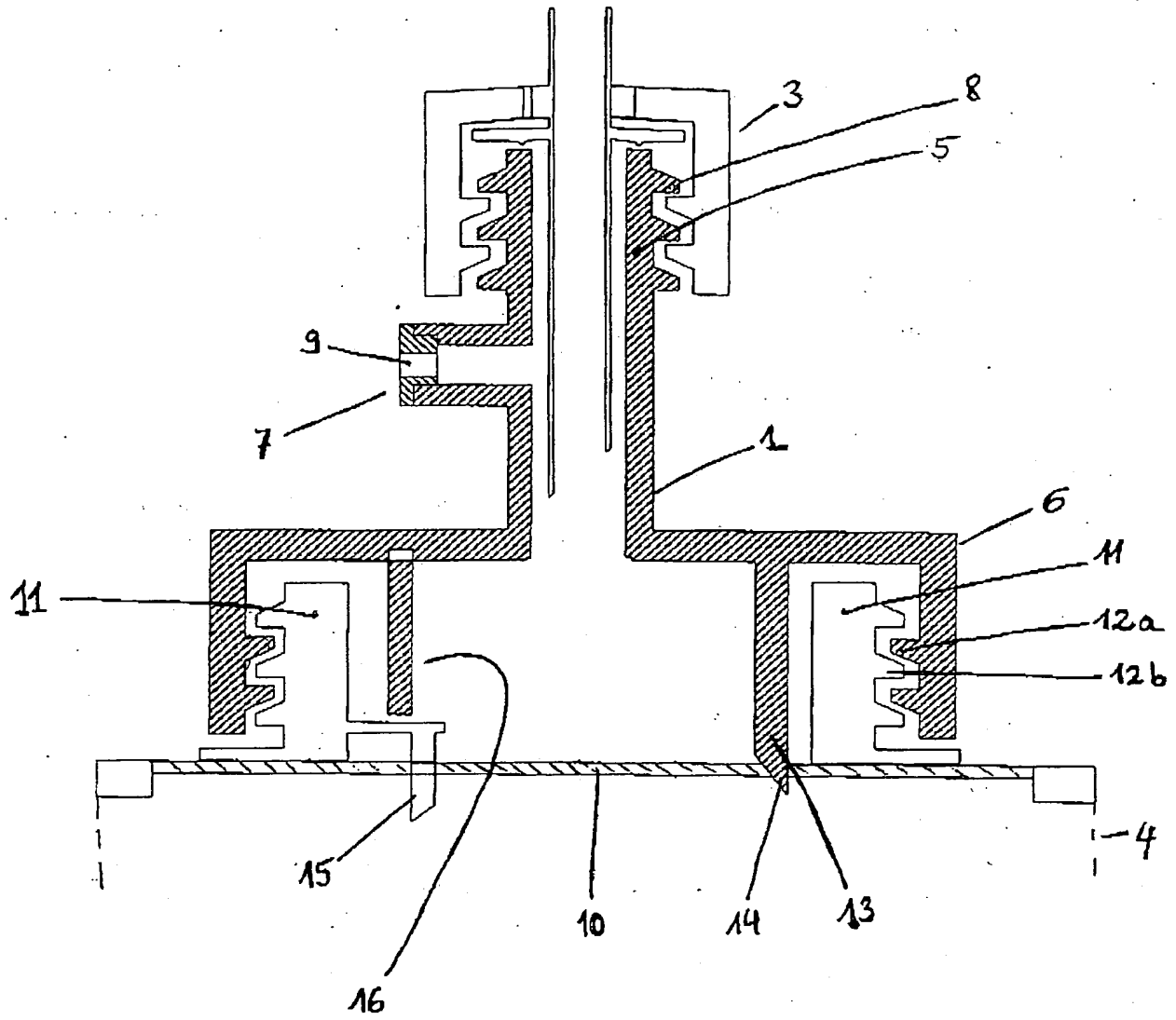


FIG. 2



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